510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

5 -1 GENERAL INFORMATION

Trade Name	SMOOTHKIT+
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	GEX
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	KIT LIPO manufactured by OSYRIS, cleared as K073617
Submitter	OSYRIS 121 Rue Chanzy, BP 90140 59260 HELLEMMES FRANCE
Contacts	Pr JAOUAD ZEMMOURI CEO jaouad.zemmouri@osyris.com Phone ; +33 (0)3 20 67 59 97 Fax: +33 (0)3 20 04 46 24 Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr

5 -2. DEVICE DESCRIPTION

SMOOTHKIT+ is a medical laser accessory. It includes a cannula crimped on an optical fiber and a handpiece. The extremity of the cannula is sharp edges rounded. The extremities of the cannula and of the optical fiber are in the same plan and there is some adhesive between the cannula and the fiber at the distal end.

5 - 3. INTENDED USE

SMOOTHKIT+ is intended for laser assisted lipolysis.

5 - 4. PERFORMANCE DATA

Performance data demonstrate the safety and effectiveness (mainly biocompatibity) of SMOOTHKIT+ for its intended use.

5 - 5. SUBSTANTIAL EQUIVALENCE

SMOOTHKIT+ has the same intended use, design and function as predicate devices KIT LIPO manufactured by OSYRIS.

Summary preparation date: July, 10, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Osyris
c/o Jaquad Zemmouri
121 Rue Chanzy, BP 90140
Hellemmes, France F59260

Re: K082004
Trade/Device Name: Smoothkit+
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 26, 2008
Received: August 28, 2008

Dear Mr. Zemmouri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K08 2004

Device Name: **SMOOTHKIT+**

Indications for Use:
SMOOTHKIT+ is intended for laser assisted lipolysis.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
✓		_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K08 2004